

### **REMARKS**

The Official Action dated August 15, 2005 has been carefully considered. It is believed that the present Amendment places the application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 25-46 are amended for various matters of form in order to more clearly define the invention. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claims 34, 35 and 44-46 were rejected under 35 U.S.C. §112, first paragraph, on the basis that the specification, while enabling for a Timothy grass Phl p2 pollen allergen specific human IgE Fab for detection assay and for standardization of allergen extract using Timothy grass Phl p2 pollen specific antibody comprising a heavy chain consisting of the amino acid sequences shown in SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9, and a light chain consisting of the amino acid sequence as shown in SEQ ID NO: 10, SEQ ID NO: 11 or SEQ ID NO. 12, respectively, does not reasonably provide enablement for any vaccine against any type I allergy comprising any group II allergen specific human IgE Fab having a heavy chain and a light chain as indicated, a method for passive immunotherapy of any type I allergy comprising administering a Phl p2-specific IgE Fab as set forth in claim 35, or any vaccine against any type I allergen as set forth in claim 44.

This rejection is traversed and reconsideration is respectfully requested. Initially, Applicants note that claims 34 and 40 are directed to vaccines, and claim 35 is directed to a method for passive immunotherapy, while claims 45 and 46 are directed to a grass pollen group II allergen specific human IgE Fab. As claims 45 and 46 are directed to the IgE Fabs, it is believed that these claims are improperly included within the rejection, particularly since

the Examiner appears to indicate that the specification is enabling for the IgE Fab recited in each of these claims.

Moreover, claim 34 and claim 44 are directed to vaccines comprising the IgE Fab according to claim 45 and claim 46, respectively, or the corresponding complete antibody. As these claims therefore recite vaccine compositions, they are fully enabled by the present specification, without reciting any intended use thereof. Finally, claim 35 is directed to a method for passive immunotherapy of type I grass pollen allergy. Applicants submit that the teachings in the specification enable such methods. First, the Examiner is directed to the specification at page 1, wherein Phl p2 is defined as grass pollen specific IgE-Fabs. Additionally, the Examiner's attention is directed to the studies described at pages 5-16 which, as described on page 16, indicate that the Phl p2-specific IgE Fabs (grass pollen specific IgE-Fabs) have therapeutical potential, for example building of the stable defense line against intruding allergens and/or inducing a protective mucosal immunity. Accordingly, claim 35 is enabled by the present specification.

It is therefore submitted that claims 34, 35 and 44-46 are fully enabled by the present specification, in accordance with the requirements of 35 U.S.C. §112, first paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 26-29 and 40 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner objected to the term "human IgG" in claims 26, 28 and 40 as the specification discloses grafted variable regions of the IgE Fabs of the invention onto human IgG I.

This rejection is traversed and reconsideration is respectfully requested. Claim 26 and claim 40 recite an isolated grass pollen group II allergen specific antibody comprising

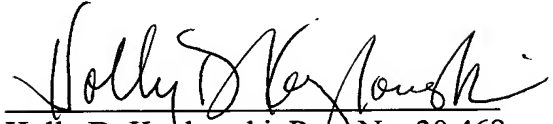
human IgG and the variable regions of the IgE Fab of claim 45 and claim 46, respectively. The specification similarly discloses that the present invention provides group II allergen specific human IgG comprising the variable regions of the indicated IgE Fabs. It is therefore submitted that claims 26 and 40, and claims 27-29 depending from claim 26, are fully supported by the specification as originally filed, whereby the rejection under 35 U.S.C. §112, first paragraph, has been overcome. Reconsideration is respectfully requested.

Finally, claims 25-46 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner objected to various recitations in the claims.

This rejection is traversed and reconsideration is respectfully requested. In view of the Examiner's comments, the claims have been amended to more clearly define the claimed invention. It is believed that the present claims overcome the various specific objections set forth in the Official Action. Applicants note that the present claims recite grass pollen group II allergen specific human IgE Fab (claims 25, 39, 45 and 46) and recite isolated grass pollen group II allergen specific antibody (claims 26 and 40). As noted above, the present specification defines Phl p2 as grass pollen specific IgE Fabs and the examples set forth in the present specification indicate that the IgE Fabs are grass pollen group II allergen specific. It is therefore submitted that the present claims are definite to one of ordinary skill in the art in accordance with the requirements of 35 U.S.C. §112, second paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §112, first and second paragraphs set forth in the Official Action, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Holly D. Kozlowski", written over a horizontal line.

Holly D. Kozlowski, Reg. No. 30,468  
DINSMORE & SHOHL LLP  
1900 Chemed Center  
255 E. Fifth Street  
Cincinnati, Ohio 45202  
(513) 977-8568

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